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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET.NO.	CONFIRMATION NO.
10/826,454	04/16/2004	Gregory J. LaRosa	10448-215011 / MPI98-129C	1309

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EXAMINER	
CROWDER, CHUN	
ART UNIT	**PAPER NUMBER**
1644	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/826,454	LAROSA ET AL.	
	Examiner	Art Unit	
	Chun Crowder	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10/18/06, 11/21/06, 02/26/07*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11 and 44-59* is/are pending in the application.

4a) Of the above claim(s) *53-56 and 59* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11, 44-52, 57, and 58* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *05/03/2004 and 04/16/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's elections of Group II, drawn to a test kit and the kit without further including a second antibody or antigen-binding fragment, filed 10/18/2006 and 02/26/2007, are acknowledged.

Applicant's species election of 1D19 antibody or antigen binding fragment thereof and MCP-1 as the ligand, filed 11/21/2006, is acknowledged. The traversal is on the ground that search ancillary reagents for detecting the presence of a complex between anti-CC chemokine receptor 2 (CCR2) and CCR2 would not be undue burden.

However, the species election set forth in the Office Action, mailed 05/22/06, does not require elections of ancillary reagents; the species election requires applicant to elect one specific antibody or antigen-binding fragment thereof that inhibits binding of one specific ligand to the receptor (e.g. see page 4 of the Office Action mailed 05/22/06). These antibodies are distinct because antibodies specific to different epitopes and inhibit binding of different ligands differ in structures, physiochemical properties and mode of action and examination of theses antibodies would require different search thus would place undue burden on the Examiner.

Therefore, the restriction requirement is still deemed proper and is made FINAL.

Claims 1-10 and 12-43 have been canceled.
Claims 11 and 44-59 are pending.

Claims 53-56 and 59 have been withdrawn from further consideration by the Examiner, under 37 C.F.R. 1.142(b), as being drawn to nonelected inventions.

Claims 11, 44-52, 57, and 58 are currently under consideration as they read on the elected invention of a test kit comprising an antibody or antigen binding fragment thereof which binds to a mammalian CCR2 and inhibits binding of chemokine MCP-1 (monocyte chemotactic protein-1) without a second antibody or antigen binding fragment thereof.

2. Claims 11 and 50 are objected to for the following informalities:

A) Claim 11 recites "one or-more ancillary reagents" on line 1 of (b). The correct recitation should be "one or more ancillary reagents".

B) Claim 50 recites "an Fab fragment, an Fab fragment" (see 2nd line of the claim 50).

C) Appropriate correction is required.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 11, 44-48, 57, and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lind et al. (US Patent 6,084,075 Reference AA on IDS filed 04/16/2004) in view of Hardiman et al. (US Patent 7,115,379).

Lin et al. teach neutralizing monoclonal antibodies MCPR-04, MCPR-05, and MCPR-06 that bind to human CCR2 and block chemokine MCP-1 binding and MCP-1 activities such as induction of Ca^{2+} in human monocytes (e.g. see columns 4-5 and Examples 3 and 4 on columns 9 and 11). Lin et al. further teach said antibodies can be used for in vitro and/or in vivo diagnostic purpose and detection of tissues and cells expressing the CCR2 and screening new drugs; furthermore, Lin et al. teach the interaction of radioactively or enzymatically labeled anti-CCR2 antibodies with CCR2 can be used for screening for therapeutic antagonistic compounds targeting CCR2 (e.g. see columns 5-6 and claim 15, in particular). Moreover, Lin et al. disclose pharmaceutical preparation comprising the antibodies and acceptable carrier (e.g. see claims 16 and 17).

The reference teaching differ from the claimed invention by not describing a kit comprising anti-CCR2 antibody and one or more ancillary reagents suitable for detecting the presence of complex between antibody or antigen binding fragment thereof and mammalian CCR2, and the antibody being lyophilized.

Hardiman et al. teach that reagents for diagnostic assays are frequently supplied in kits so as to optimize the sensitivity for the assay (e.g. see column 36); Hardiman et al. further teach a kit comprising antibodies or antigen binding fragment thereof to CX3Ckine receptor, the label, buffer, stabilizer, and materials necessary for signal production such as substrate for enzymes; the reagents in the kit are provided as a dry lyophilized powder and can be reconstituted to provide appropriate concentrations (e.g. see columns 35-36 and claims 1 and 15).

It is noted that the instant claims recite "one or more ancillary reagents" without setting forth the actual "ancillary reagents". The instant specification discloses that a kit comprising an antibody or antigen binding fragment thereof and one or more ancillary reagents suitable for detecting the presence of a complex between the antibody and the antigen CCR2 (see page 35 of the specification as-filed). However, the specification does not disclose any "ancillary reagents" that are encompassed by the instant claims. For examination purposes, the "ancillary reagents" are read as any reagents other than the anti-CCR2 antibody because reagents such as buffer are suitable for detecting the presence of a complex between an antibody and an antigen.

Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to make a kit comprising the anti-CCR2 antibodies disclosed by Lin et al. and one or more ancillary reagents suitable for detecting the presence of an antibody-antigen complex taught by Hardiman et al. for use in diagnostic assays with a reasonable expectation of success.

One having ordinary skill in the art would have been motivated to do so because the neutralizing anti-CCR2 antibodies can be used in vitro and/or in vivo for diagnostic purpose, detection of the expressing the CCR2, and screening new drugs and reagents for diagnostic assays are frequently supplied in kits comprising reagents for detection so as to optimize the sensitivity for the assay.

From the teachings of Lin et al. and Hardiman et al, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed kit for detecting the presence of a mammalian CCR2. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

5. Claim 49-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lind et al. (US Patent 6,084,075 Reference AA on IDS filed 04/16/2004) and Hardiman et al. (US Patent 7,115,379) as applied to claim 11 above, and further in view of Lam et al. (6,171,586).

The teachings of Lin et al and Hardiman et al have been discussed, supra. Lin et al. further teach that the anti-CCR2 antibodies can be used to treat diseases such as inflammation and rheumatoid arthritis (see column 6, in particular).

The teachings of the references differ from the claimed invention by not describing human antibody, antigen-binding fragments, humanized antibody and recombinant antibody.

Lam et al. teach antibody formulation comprising antibodies specific for chemokines including RANTES (e.g. see column 10); Lam et al. further teach the antibody formulation can include antigen-binding fragments Fv, Fab, Fab', and $F(ab')_2$, (e.g. see columns 7), recombinant antibodies such as humanized and human antibodies (e.g. see columns 13 and 14). Lam et al. further teach that the antibodies can subject to one or more biological activity assays to select an antibody with beneficial properties for therapies; for example, Lam et al. teach well known immunoassays such as ELISA comprising antibody and one or more reagents (e.g. HRP-labeled anti-human antibody and substrate for colorimetric detection) suitable for detecting the presence of antigen-antibody complex (e.g. see column 18).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to make a kit comprising the anti-CCR2 antibodies disclosed by Lin et al, one or more ancillary reagents suitable for detecting the presence of an antibody-antigen complex taught by Hardiman et al, and to include antigen-binding fragments Fv, Fab, Fab', and $F(ab')_2$, recombinant antibodies such as humanized and human antibodies in the kit with a reasonable expectation of success.

One having ordinary skill in the art would have been motivated to do so because the neutralizing anti-CCR2 antibodies are therapeutic and can be used in vitro and/or in vivo for diagnostic purpose, detection of the expressing the CCR2, and screening new drugs; reagents for diagnostic assays are frequently supplied in kits comprising reagents for detection so as to optimize the sensitivity for the assay and antigen-binding fragments, humanized and human antibodies can be used in well known immunoassays such as ELISA.

From the teachings of Lin et al, Hardiman et al and Lam et al, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed kit comprising anti-CCR2 antibody such as human antibody, antigen-binding fragments, humanized antibody and recombinant antibody for detecting the presence of a mammalian CCR2. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

6. No claim is allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chun Crowder whose telephone number is 571-272-8142. The examiner can normally be reached on 8:30-5:00. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Chun Crowder, Ph.D.
Patent Examiner
March 6, 2007

PHILLIP GAMBEL, PH.D
PRIMARY EXAMINER
TC 1600
4/11/07